

# Information

## Short Stay Surgical Centers

*A Statement by the California Medical Association  
Commission on Health Facilities*

AMBULATORY SURGICAL CENTERS are an experimental way of providing surgical care. They should meet the standards of care set for the surgical departments of general hospitals by the Joint Commission on Accreditation of Hospitals and the Medical Staff Survey Committee of the CMA. Before a center is opened, the following criteria should be established by the center, local medical society and health planning council.

1. There shall be an arrangement for hospital transfer and backup including methods of transportation and communication between center and hospital.

2. There shall be a method of screening patients appropriate for the center.

3. Adequate patient records shall be maintained.

4. There shall be a method of checking the credentials of the physicians practicing in the center and standards set for granting privileges to use the center. In no case shall surgical privileges be granted a physician exceeding those granted to him by any of the hospitals in which he has staff privileges, and these should be consistent with the privileges he holds in various community hospitals.

5. There shall be peer review and reporting to local medical society, and there should be a standing Medical Audit Committee of Physicians who regularly review the procedures and privileges of the staff.

6. Cooperating hospitals shall be in *close* proximity to any freestanding surgicenter. Hospitals, in cooperation with comprehensive health planning, shall be encouraged to develop surgicenters as an integral part of their complex where appropriate.

Approved by the Council of the California Medical Association, May 4-5, 1973.

## Selected Items from the FDA Drug Bulletin

### Postcoital Diethylstilbestrol

IN AGREEMENT WITH ITS extragovernmental physician-advisers, FDA has approved, under restricted conditions, postcoital (contraceptive) use of diethylstilbestrol (DES), a synthetic estrogen. Adequate evidence to support the use of any other estrogen for this purpose is not presently available.

The Agency considers the use of DES for this purpose to be safe only as an emergency measure (in situations such as rape, incest, or where, in the physician's judgment, the patient's physical or mental well-being is in jeopardy) and explicitly warns against its routine or frequent use as a contraceptive.

Physicians are urged, prior to prescribing DES for this purpose, to inform patients (or guardians) fully of the possible side effects of the drug, and of alternative measures available and their hazards, so that the patient may participate in an informed way in the decision to use the drug. Pregnancy should be ruled out by appropriate tests prior to instituting therapy, so that no unnecessary exposure of a fetus to DES occurs.

The efficacy of DES in preventing pregnancy depends upon the time-lapse after coitus and dosage of the drug. The currently recommended dosage is 25 mg twice a day for 5 continuous days beginning, preferably, within 24 hours and not later than 72 hours after exposure. When this dosage is given within the specified time interval after sexual intercourse, DES is highly effective in preventing conception. But the patient must be warned to take the full course of the drug in spite of the nausea which commonly occurs, if it is to be effective.

There is at present no positive evidence that the restricted postcoital use of DES carries a significant carcinogenic risk either to the mother or fetus. However, because existing data support the possibility of delayed appearance of carcinoma in females whose mothers have been given DES later in pregnancy, and because teratogenic and other

adverse effects on the fetus with the very early administration recommended are ill understood, failure of postcoital treatment with DES deserves serious consideration of voluntary termination of pregnancy.

Before prescribing, the physician should be familiar with the complete FDA-approved labeling on products intended for this use.

FDA Drug Bulletin, May 1973

## U-100 Insulin

U-100 INSULIN, which is now being made available, offers distinct advantages over U-40 and U-80 preparations. It is offered as regular and in a variety of long-acting forms.

Each milliliter of U-100 insulin contains 100 units of insulin. The drug is dispensed in 10 ml (1,000 unit) vials.

It is important that patients for whom this new insulin is prescribed be instructed in the use of the new 1 ml U-100 syringe. Each calibration of this syringe represents 2 units or 0.02 ml. Every 0.1 ml or 10 unit calibration is marked with corresponding numerals.

When small doses are given or accuracy down to 1 unit is necessary, a 0.35 ml (35 unit) syringe is available in which each calibration represents 0.01 ml or 1 unit.

U-40 and U-80 insulins will continue to be marketed until the use of U-100 is generally accepted.

FDA Drug Bulletin, May 1973

## Tardive Dyskinesia Associated with Antipsychotic Drugs

TARDIVE DYSKINESIA, a syndrome characterized by rhythmical involuntary movements, may be associated with the use of phenothiazines and certain other antipsychotic medications. The condition appears in some patients on long-term therapy, sometimes even after it has been discontinued. FDA recommends that the antipsychotic medications be withdrawn immediately if the syndrome appears, and has added the following statement to the ADVERSE REACTIONS section of the package inserts of antipsychotic drugs:

"Tardive dyskinesia may appear in some patients on long-term therapy or may occur after drug therapy with phenothiazines and related agents has been discontinued. The risk appears to be greater in elderly patients on high-dose therapy, especially females. The symptoms are persistent and in some

patients appear to be irreversible. The syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, chewing movements). Involuntary movements of the extremities sometimes occur. There is no known treatment for tardive dyskinesia; antiparkinsonism agents usually do not alleviate the symptoms. It is advised that all antipsychotic agents be discontinued if the above symptoms appear. If treatment is reinstituted, or dosage of the particular drug increased, or another drug substituted, the syndrome may be masked. It has been suggested that fine vermicular movements of the tongue may be an early sign of the syndrome, and that the full-blown syndrome may not develop if medication is stopped when lingual vermiculation appears."

At times a choice between two evils must be made, as when on the one hand a patient's psychosis worsens without a given antipsychotic drug whereas on the other hand administration of the drug causes severe side effects. Use of the lowest possible dose of the drug adequate to control symptoms appears to be one possible answer. Alternatively, the patient may be given another drug chemically least like that causing the dyskinesia.

The incidence of tardive dyskinesia is not well established. It is rarely seen in acute psychiatric units, even in patients with recurring schizophrenia. But incidence rates of about 20 percent have been reported in older, institutionalized, chronically ill patients. Perhaps 3 percent to 6 percent of patients in a mixed psychiatric population receiving neuroleptics exhibit some aspects of the syndrome at one time or another.

The physician may be able to reduce the risk of producing tardive dyskinesia by:

1. Minimizing the unnecessary use of neuroleptic medication (especially in high doses) in chronically ill patients. Many of the latter can be satisfactorily maintained for long periods without antipsychotic drugs. Drug holidays are advised in patients receiving long-term medication.
2. Discontinuing neuroleptics, if possible, at the first sign of abnormal oral or lingual movements or other possible manifestations of tardive dyskinesia.
3. Observing these precautions carefully in the elderly (females especially) and probably in all patients over age 50.

FDA Drug Bulletin, May 1973